134 Anita Avenue
Mt. Prospect, IL 60056
May 17, 1999

Dockets Management Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

To the FDA:

I oppose the draft MOU being proposed by the FDA for the following reasons:

1. Pharmaceutical corporations primarily manufacture synthetic estrogens. Synthetics have a different chemical structure than natural estrogen and they have adverse side effects. If a woman wants to take a natural estrogen, she has very limited options from pharmaceutical manufacturers.
2. The only natural estrogen made by pharmaceutical companies is estradiol, and all the pills/patches they make are too high in dosage. Taking these causes elevated blood estrogen levels which then predisposes a woman to breast and endometrial cancer. Low dosage estradiol is only available from local compounding pharmacies.
3. Other natural estrogens (estrone or estriol) are not available from commercial pharmaceutical manufacturers nor most local pharmacies.
4. There are only a few pharmacies in the US that compound natural estrogens. If women are not allowed to purchase across state borders, how will they get the prescribed medications that they need?

The draft MOU uses the phrase "inordinate amount" to limit the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies. This restriction will adversely affect women. Please thoughtfully reconsider your decision.

Sincerely,

Barbara Hanson

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